ProCare Rx

URGENT NOTICE

TYPE: Drug Recall

Potential Inaccurate Dosage Delivery

Drug Name: **Auvi-Q (epinephrine injection, USP)**

Audience: Pharmacy, Patient

Date: **10/29/2015**

ISSUE

Sanofi US is voluntarily recalling all Auvi-Q (epinephrine injection, USP). The recall involves all Auvi-Q currently on the market and includes both the 0.15mg and 0.3mg strengths for hospitals, retailers, and consumers. This includes lot number 2299596 through 3037230, which expire March 2016 through December 2016. The products have been found to potentially have inaccurate dosage delivery.

As of October 26, 2015, Sanofi has received 26 reports of suspected device malfunctions in the US and Canada. None of these device malfunction reports have been confirmed. In these reports, patients have described symptoms of the underlying hypersensitivity reaction. No fatal outcomes have been reported among these cases.

If a patient experiencing a serious allergic reaction (i.e., anaphylaxis) did not receive the intended dose, there could be significant health consequences, including death, as anaphylaxis is a potentially life-threatening condition.

BACKGROUND

Auvi-Q (epinephrine injection, USP) is used to treat life-threatening allergic reactions (anaphylaxis) in people who are at risk for or have a history of these reactions. Auvi-Q is packaged with two active devices and one trainer device in a corrugate box. Auvi-Q was distributed throughout the United States via wholesalers, pharmacies, and hospitals. All Auvi-Q is being recalled.

RECOMMENDATION

Sanofi US is notifying its distributors and customers, including doctors, pharmacies, wholesalers, and other customers in the supply chain by letter, fax, email, and phone calls, and is arranging for return and reimbursement of all recalled products.

Patients should call 877-319-8963 or 866-726-6340 to arrange for a return packet to be shipped to them. In approximately five days, they will receive a prepaid mailing envelope, which will include a return form and a prepaid mailing label.